

BUTTIEZZZ DAILY- zinc oxide spray
Fortunique B.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Zinc Oxide 4%

Purpose

Skin protectant

Uses

Helps treat and prevent diaper rash

Helps seal out wetness

Warning

For external use only

When using this product

Avoid contact with eyes

Stop use and contact a Doctor if:

Condition worsens

Symptoms last more than 7 days or clear up and occur again within a few days

Not to be applied over deep or puncture wound, infection or lacerations

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Change wet or soiled diapers promptly

Shake well before use

Make sure the skin is clean and dry before use. Use a sweeping movement to spray-on the cream in a thin and uniform layer on the buttocks

Allow to dry

Use a spraying distance approximately 2 to 3 inches

Apply Buttiezzz Daily liberally as often as necessary or at every diaper change

Other information

Store at room temperature below 77° F

Inactive Ingredients

Water(Aqua)

Coco-Caprylate/Caprato

Glycerin

Alkyl- Alcohols

Alkyl Glucoside

Propylene glycol

Cocoglycerides

Caprylyl Glycol

Capryl-Hydroxamic acid

Chamomilla Recutita(Matricaria)Flower Extract

Calendula Officinalis Flower Extract

Silica

Oleic Acid

Principle Display Panel.50ml Bottle Spray carton

Buttiezzz DAILY
baby bottom cream spray

Buttiezzz Daily

Buttiezzz Daily is a pump spray-on cream for daily use to care for baby's bottoms and protect preventatively against the diaper content. The skin caring cream can be sprayed directly onto baby's bottom and therefore the skin does not need to be touched. The cream absorbs directly into the skin and the Zinc Oxide leaves an effective protective layer which shields baby's bottom against the diaper content. The added Calendula and Chamomile extracts help to relax the skin and to promote the natural recovery of the skin. The use of the pump spray also helps to prevent (re)contamination.

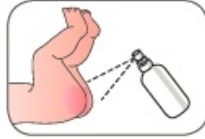
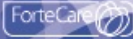
Manufactured by:
ForTunique B.V., Lindenlaan 31C,
6584 AC Molenhoek (LB),
The Netherlands
www.fortunique.com

Distributed by: Nutritional Products
International, Boca Raton, FL

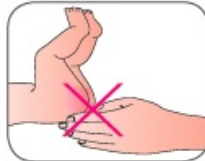
Questions? Call 561-544-0719.

Made in The Netherlands

Butiezzz Daily is a product of the
ForteCare range of products.



Easy to use, just spray-on, one hand use. Sprays a perfectly thin layer. Very economical to use, 1:3 (spray versus tube/jar)



No need to touch the skin.



Hygienic (no risk of recontamination of the product: can be used by several people).

See package insert. No added coloring agents and fragrance. Paraben and preservative free.

Buttiezzz DAILY
baby bottom cream spray

Soothes baby bottoms

Skin protectant

Net.Wt. 1.7 fl. oz. (50mL)

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide 4%.....	Skin Protectant
Uses	
<ul style="list-style-type: none"> • Helps treat and prevent diaper rash. • Helps seal out wetness. 	
Warnings	
<ul style="list-style-type: none"> • For external use only. 	
When using this product	
<ul style="list-style-type: none"> • Avoid contact with eyes. 	
Stop use and contact a doctor if:	
<ul style="list-style-type: none"> • Condition worsens. • Symptoms last more than 7 days or clear up and occur within a few days. • Not to be applied over deep or puncture wounds, infection or lacerations. 	
Keep out of reach of children.	
<ul style="list-style-type: none"> • If swallowed, get medical help or contact a Poison Control Center right away. 	
Directions	
<ul style="list-style-type: none"> • Change wet or soiled diapers promptly. • Shake well before use. • Make sure the skin is clean and dry before use. Use a sweeping movement to spray-on the cream in a thin and uniform layer on the buttocks. • Allow to dry. • Use a spraying distance of approximately 2 to 3 inches. • Apply Buttiezzz Daily liberally as often as necessary or at every diaper change. 	
Other Information	
Store at room temperature below 77°F.	
Inactive Ingredients	
Water (Aqua), Coco-Caprylate/Caprate, Glycerin, Alkyl-alcohols, Alkyl glucoside, Propylene glycol, Cocoglycerides, Caprylyl glycol, Caprylhydroxamic acid, Chamomilla recutita (matricaria) flower extract, Calendula officinalis flower extract, Silica, Oleic Acid.	

03036127v2



Batch no:

Exp. date:

BUTTIEZZZ DAILY

zinc oxide spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70359-410 1

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
C14-22 ALCOHOLS (UNII: B1K89384RJ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEIC ACID (UNII: 2UMI9U37CP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
CHAMOMILE (UNII: FGL3685T2X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70359-4101-1	1 in 1 CARTON	01/19/2016	
1		50 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/19/2016	

Labeler - Fortunique B.V. (407788616)**Registrant** - Fortunique B.V. (407788616)**Establishment**

Name	Address	ID/FEI	Business Operations
Fortunique B.V.		407788616	manufacture(70359-4101)